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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,412	06/12/2000	GUNTHER SCHNEIDER	BEIERSDORF6	9863

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EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,412

Applicant(s)

SCHNEIDER ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 2, 2003 has been entered. Claims 11-43 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 41-43 introduces a new concept of excluding acyl lactylates from the present invention. It is well established in patent law that negative limitation must have support in the disclosure. See Ex parte Grasselli, 231 U.S.P.Q. 393, 394 (Bd. App. 1983) (stating express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded). In this case, there is no support in the

original disclosure that applicants have contemplated a composition comprising acyl lactylates, and thus constitutes a new matter.

Warning

Applicant is advised that should claim 42 be found allowable, claim 43 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 11-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aronson et al. (US 4,606,913) ("Aronson") in view of Jackman et al. (US 6,352,998 B2) ("Jackman") and Schneider et al. (US 5780445) ("Schneider").

Aronson et al. teaches a topical emulsion composition with electrolyte in aqueous phase. The reference further teaches that the incorporation of sufficient amount of electrolyte into the aqueous phase of the emulsion results in the improved stability of the emulsion, i.e., reduced chance of phase separation for extended periods of time. The stability of the emulsions is described in detail in col. 19, lines 21 – 57. The reference teaches using emulsifiers in the amount of 0.5 to 5 % by weight of the emulsion. See col. 8, lines 25 – 34. Conventional emulsifiers such as sorbitan

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isostearate (Arlacel 987), mono and diglycerides of fatty acids, are disclosed in col. 5, line 33 – col. 6, line 17. See instant claims 11(i) and 23 (i). The reference further teaches that a skilled worker would have been able to optimize the kinds and quantity of electrolytes to be used via simple experiments. See col. 8, lines 50 – 67. The electrolytes are disclosed in col. 9, line 9 – col. 10, line 10. While the reference lacks a specific mention of employing fatty alcohol in instant claims 11 (iii) and 21 (iii), it is noted that the reference states, “any emulsifier whose ability to stabilize a [high-internal phase emulsion] is improved by the inclusion of an electrolyte in the aqueous phase of said emulsion is within the contemplated invention.” See col. 6, lines 1 – 7. See col. 5, lines 34 – 41, which teaches to use conventional emulsifiers used in low or mid-internal – phase emulsions, particularly the nonionic emulsifiers having HLB values of about 1 to about 7. Examiner thus takes the position that the Aronson reference generally teaches the concept of achieving increased stability of an emulsion having electrolytes in its aqueous phase by incorporating conventional emulsifiers well known in the art.

Jackman teaches topical pharmaceutical compositions. The reference teaches that the preferred emulsifiers include glycerine monostearate, sorbitan mono stearate (Arlacel 60), sorbitan mono oleate, glycerine mono stearate (Imwitor 960), cetyl alcohol, and mixture thereof. See col. 5, lines 50 – 60. The reference further teaches that O/W emulsions require emulsifiers having HLB of 4 to 8. Examples 1 and 2 show O/W emulsions, each comprising oleyl alcohol, cetyl alcohol, stearyl alcohol, sorbitan monostearate, and glycerine mono stearate. The weight ratio of glycerine mono stearate and sorbitan monostearate for each formulation is 3:2. See instant claims 18,

19, 37, and 38. As to claim 20 and 39, differences in concentration ordinarily will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Jackman, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation.

Aronson and Jackman, discussed above, fail to teach glyceryl stearate citrate.

Schneider teaches a topical O/W emulsion formulation comprising glyceryl stearate citrate. See Examples 10 and 11; instant claims 21 and 40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the emulsion in Aronson by adding the mixture of glycerine monostearate, sorbitan monostearate, and cetyl alcohol, as suggested by Jackson, because of the expectation of successfully producing a stabilized oil-in-water emulsion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted glyceryl stearate citrate, as motivated by Schneider, because of the expectation of successfully producing an oil-in-water emulsion having similar or enhanced stability. Acyl lactylate is not mentioned in the prior arts.

Response to Arguments

Applicant's arguments with respect to claims 11-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
March 10, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

3/10/03